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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,347	09/25/2001	J. Fernando Bazan	DX0903K1	9754

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/963,347	BAZAN ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-32* is/are pending in the application.

4a) Of the above claim(s) *25-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24, 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 22-24 have been amended and claim 32 has been added as requested in the amendment filed on May 25, 2004. Claims 21-32 are pending in the instant application.

Claims 25-29 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made by original presentation, see section 3 of office action mailed on December 08, 2203

Claims 21-24 and 30-32 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on May 25, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 22-24 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for those reasons of record in section 6 of Paper mailed on December 08, 2003. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that "[t]he present specification describes distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (middle at page 8 of the Response). Applicant refers to pages 12, 15 and 16 of the instant specification, which contain statements that fragments of amino acid sequence of SEQ ID NO: 4, as well as peptides having at least 35% identity would possess the activity of the full length molecule of SEQ ID NO: 4. Applicant further submits that because IL-B50 of the instant invention is structurally related to IL-7, the distinguishing identifying characteristics of these two cytokines are the same (bottom at page 8, continuing to page 9 of the Response). These arguments have been fully considered but are not deemed to be persuasive for the following reasons.

The instant claims are drawn to polypeptides having at least 80% sequence identity with or fragments of a particular disclosed sequence. The claims do not require that the polypeptide possess any particular conserved structure or other disclosed distinguishing feature. The claims only require the polypeptide to be capable of binding a putative IL-B50 receptor, function and biological significance of which at the time of invention appears to be not disclosed. Thus, one would reasonably conclude that the claims are drawn to a genus of polypeptides that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the

claims is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 4, but not the full breadth of the claim meets the written description provision of 35

U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

6. Claims 22-24 and 30-32 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide encoded by a nucleic acid molecule of SEQ ID NO: 3, does not reasonably provide enablement for any other molecular embodiment structurally related to the polypeptide of SEQ ID NO: 4. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 22-24 are directed to polypeptides, which are fragments or have at least 80% identity to a polypeptide of SEQ ID NO: 4 capable of binding an IL-B50 receptor. However, the instant specification fails to provide enough guidance for one skilled in the art on how to make and use the claimed proteins, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

The nature of the invention is the demonstration that IL-B50 polypeptide of SEQ ID NO: 4 is capable of inducing chemokine expression of monocytes and proliferation of dendritic cells

(pages 64-69 of the instant specification). The instant specification does not disclose the significance of IL-B50 receptor, its biological function or expression pattern. The art does not provide any information on how to identify or isolate IL-B50 receptor to use in a binding assay. Therefore, one skilled in the art would have to solely rely on the instant disclosure for guidance to practice the full scope of Applicant's invention. While the skill level in the art is high, the level of predictability is low. The sole working examples in the specification, as originally filed, pertain to the production an use of the full length polypeptide of SEQ ID NO: 4. The instant specification fails to provide any guidance for a skilled artisan on how to make a polypeptide with a limited structural similarity to the polypeptide of SEQ ID NO: 4, such polypeptide being able to bind a putative IL-B50 receptor. Without this critical information, it would appear that Applicant provides a single finding, the disclosure of the IL-B50 polypeptide of SEQ ID NO: 4, and then presents an invitation to experiment to determine what other fragments of this amino acid structure would also bind IL-B50, and then to assay for use of these polypeptides as pharmaceuticals.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:
"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the

enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and make and use the claimed polypeptides without first making a substantial inventive contribution.

7. Claims 21-24 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for those reasons of record in sections 8 and 9 of Paper mailed on December 08, 2003. Briefly, the claims employ the term "IL-B50" as a limitation with reference to a putative receptor. The instant specification does not identify that property or combination of properties which are unique to and, therefore, definitive of a "IL-B50". Therefore, an artisan cannot definitively determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation, such "binding an IL-B50 receptor".

Claim Rejections - 35 USC § 102

8. Claims 21-24 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al. for those reasons of record in section 11 of Paper mailed on December 08, 2003.

Applicant argues that "the Sims patent" cannot serve as 102(e) reference because the instant invention was fully disclosed in provisional application 60/101,318 ('318) and, therefore,

the effective filing date of the instant application is 09/21/1998, which is before the filing date of the Sims application (page 10 of the Response). These arguments were fully considered but are not persuasive for the following reasons.

Analysis of '318 application revealed that the function of IL-B50 at the time of filing was disclosed as follows: "It is likely that IL-B50 has either stimulatory or inhibitory effect on hematopoietic cells, including, e.g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, hematopoietic progenitors, etc." (middle at page 9 of 60/101,318 application). Because the '318 application fails to disclose specific utility of IL-B50 ("either stimulatory or inhibitory effect" does not provide for specific activity), and because the specific, substantial and credible utility of the instant IL-B50 is only disclosed in the instant specification, the effective filing date for the instant invention remains the filing date of the instant application, 09/25/2001, which makes "the Sims patent" proper 102(e) reference.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ɔ 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.

OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER